## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

IMS HEALTH INCORPORATED, a Delaware	
corporation and VERISPAN, LLC, a Delaware	)
limited liability company,	)
	)
Plaintiffs,	)
	) Case No. 06-CV-280-PB
vs.	
	)
KELLY A. AYOTTE, as Attorney General of	)
the State of New Hampshire,	)
	)
Defendant.	)
	_)

## Declaration of James Mahon in Support of Plaintiffs' Motion for Preliminary Injunction

- I, James Mahon, hereby declare under penalty of perjury that the following is true and correct:
- 1. I am over 18 years of age. I am General Manager of IMS Health Incorporated ("IMS Health") for the Americas region. I have personal knowledge of the information contained in this declaration.
- 2. After the New Hampshire Legislature passed the 2006 N.H. Laws 328, codified as N.H. Rev. Stat. Ann. §§ 318:47-f & 318:47-g & 318-B:12, IV (2006) (referred to herein as "the Prescription Restraint Law"), but before it was signed into law by the Governor, I and other IMS Health officers and employees carefully reviewed the law to try to understand whether and how it would have an impact on our business. It was clear to me that however the statute would be interpreted and applied it would stop much of the work that IMS Health currently does with prescriber-identifiable data from New Hampshire prescription records, but I also was interested in obtaining clarification of some of the language in the statute that appeared to be vague or

ambiguous.

- 3. Through our attorneys in Concord, New Hampshire, Orr & Reno, P.A., we asked a representative of the New Hampshire Attorney General's Office to meet with us to discuss how the law might be applied to IMS Health. Assistant Attorney General Richard Head had spoken to the Legislature about the legislation and he graciously agreed to speak with us about the matter. In advance of meeting with him, IMS Health provided him with a letter which set forth questions concerning the law. This letter is attached to this Declaration as Exhibit A.
- 4. On June 8, 2006, Orr & Reno attorneys Jeffrey C. Spear and James P. Bassett and I met with New Hampshire Asst. Atty. Gen. Richard Head to discuss how the State would interpret and enforce the Prescription Restraint Law. Harvey Ashman, Vice President & Associate General Counsel for IMS Health also participated in the meeting by telephone.
- 5. At the outset of the meeting, Asst. Atty. Gen. Head stressed that nothing that he said at the meeting would bind the Attorney General's office or prevent it from pursuing any action inconsistent with any statements he might make. We indicated our understanding of this, but asked if he would proceed with an informal discussion of the law so that IMS Health might have a better understanding of the risks that the law presented to IMS Health if the company continued with its normal business practices.
- 6. Asst. Atty. Gen. Head discussed with us the specific questions about the Prescription Restraint Law that we had raised in our letter and confirmed that the Attorney General would enforce all provisions of the law and defend its constitutionality if it were challenged.
- 7. Asst. Atty. Gen. Head tried to be helpful, yet he was unable to provide us with any assurance that IMS Health could not or would not be prosecuted if it continued its existing

business practices. After the meeting with Asst. Atty. Gen. Head, I was convinced that criminal and civil prosecutions would be brought if IMS Health continued to acquire from pharmacies and

similar entities New Hampshire prescription records containing prescriber-identifiable data and

continued to license that information to pharmaceutical companies so that they could use the

information for advertising, marketing, promotion, or any activity that could be used to influence

sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior

of an individual health care professional, or evaluate the effectiveness of a professional

pharmaceutical detailing sales force.

8. IMS Health has concrete plans to engage immediately in activity that it

reasonably believes would result in criminal and civil prosecutions under the Prescription

Restraint Law. Those concrete plans are to continue the purchasing and licensing of patient-de-

identified prescription information from covered entities for commercial purposes that are

ostensibly prohibited by the Prescription Restraint Law.

9. These are the same concrete plans that IMS Health has executed for the last 13

years. IMS Health has ceased execution of these plans solely due to the passage of the

Prescription Restraint Law and the real threat that IMS Health will be subjected to serious

criminal and civil fines and injunctions if it executes these plans.

Executed on July 27, 2006, in Plymouth Meeting, Pennsylvania.

\_\_\_\_\_\_/<u>s/ James Mahon</u>
James Mahon

Exhibit A



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June 1, 2006

Malcolm McLane (Retired)

Ronald L. Snow William L. Chapman George W. Roussos Howard M. Moffett James E. Morris John A. Malmberg Martha Van Oot Douglas L. Patch Connie L. Rakowsky Jill K. Blackmer James P. Bassett Emily Gray Rice Steven L. Winer Peter F. Burger Lisa Snow Wade Jennifer A. Eber Pamela E. Phelan Connie Boyles Lane Jeffrey C. Spear Judith A. Fairclough James F. Laboe

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## VIA HAND DELIVERY

Richard Head, Esq. Senior Assistant Attorney General New Hampshire Department of Justice 33 Capitol Street Concord, NH 03301

RE: House Bill 1346

Dear Richard:

Thank you for agreeing to meet with me and representatives of my client, IMS Health Incorporated, regarding the recently passed legislation that regulates records relative to prescription information containing patient-identifiable and physician- identifiable data.

In advance of that meeting, I am providing you with this outline of my client's concerns about the new legislation and how it might be interpreted. Nothing in this letter should be regarded a waiver of the attorney-client or work product privilege or otherwise waiving any rights of our clients.

We seek the Attorney General's guidance, to the extent that you are able to provide it, regarding how this new statute may be interpreted and enforced. We understand that you may not be able to provide definitive guidance and that others who have standing to enforce the statute may not agree with the Attorney General's viewpoint, but my client feels that it would be beneficial at least to have a sense from you as to how the new law may be regarded as affecting certain of its information gathering and utilization practices.

IMS is a leading provider of information, research, and analysis to the health care industry, with data collection and reporting activities in over 100 countries. Founded in 1954, the company receives and processes vast quantities of health care data. In the United States alone, the company collects information from tens of thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes millions of records each week (de-identified with respect to patient information). IMS Health has been

collecting information from New Hampshire pharmacies for decades. IMS purchases prescription information containing physician-identifiable data from various sources in New Hampshire. The information IMS purchases from New Hampshire pharmacies does not include any patient-identifiable information. In this way, patient privacy is always safeguarded. IMS historically has used the data, together with other data regarding the location and specialty of prescribing physicians, to compile reliable information concerning pharmaceuticals prescribed by specific physicians and distributed / dispensed within various geographic areas.

Through its data gathering and analysis, IMS has become an objective, unbiased source of information for pharmaceutical and biotech companies, governments, public health institutions, drug safety and patient advocacy organizations, medical and academic researchers, healthcare regulatory agencies, and industry observers, including journalists and the financial community. IMS information and expertise has played a critical role in advancing healthcare research projects across the globe -- from public policy studies that seek to allocate healthcare resources more equitably, to assessments of drug therapies and outcomes and patient trends and treatments.

We are concerned that the new legislation could have a significant impact on the ability of IMS to continue to provide such valuable services and that the law may, in fact, transgress constitutional limitations on legislation limiting the free flow of information. We also recognize, however, that a narrow construction of the statute could avoid at least some of the constitutional issues raised by the statute and might limit the statute's impact on our client's business. The courts obviously have the ultimate say regarding how the statute will be interpreted, but since the views of your office often have great persuasive weight in the courts, your sharing of those views with us, formally or informally, would help us better understand what our client must do to comply with the statute. For ease of reference in our discussions, I have divided the first part of the new legislation into the following nine sections:

## 318:47-f Prescription Information to be Kept Confidential.

- [1] Records relative to prescription information containing
  - [a] patient-identifiable and
  - [b] prescriber-identifiable data
- [2] shall not be
  - [a] licensed,
  - [b] transferred,
  - [c] used, or
  - [d] sold
- [3] by any
  - [a] pharmacy benefits manager,
  - [b] insurance company,

- [c] electronic transmission intermediary,
- [d] retail, mail order, or Internet pharmacy or
- [e] other similar entity,
- [4] for any commercial purpose, except for the limited purposes of
  - [a] pharmacy reimbursement;
  - [b] formulary compliance;
  - [c] care management;
  - [d] utilization review by
    - [i] a health care provider,
    - [ii] the patient's insurance provider or
    - [iii] the agent of either;
  - [e] health care research; or
  - [f] as otherwise provided by law.
- [5] [a] Commercial purpose includes, but is not limited to,
  - [i] advertising,
  - [ii] marketing,
  - [iii] promotion, or
  - [iv] any activity
  - [b] that could be used to
    - [i] influence sales or market share of a pharmaceutical product,
    - [ii] influence or evaluate the prescribing behavior of an individual health care professional, or
    - [iii] evaluate the effectiveness of a professional pharmaceutical detailing sales force.
- [6] Nothing in this section shall prohibit
  - [a] the dispensing of prescription medications to a patient or to the patient's authorized representative;
  - [b] the transmission of prescription information between an authorized prescriber and a licensed pharmacy;
  - [c] the transfer of prescription information between licensed pharmacies;
  - [d] the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred;
  - [e] care management educational communications provided to a patient about:
    - [i] the patient's health condition,
    - [ii] adherence to a prescribed course of therapy or other information about the drug being dispensed,
    - [iii] treatment options, or
    - [iv] clinical trials.

- [7] [a] Nothing in this section shall prohibit the
  - collection. [i]
  - [ii] use,
  - [iii] transfer or
  - [iv] sale
  - [b] of patient and prescriber de-identified data by
    - zip code, [v]
    - [vi] geographic region or
    - medical specialty [vii]
  - for commercial purposes.  $\begin{bmatrix} c \end{bmatrix}$
- In addition to other appropriate remedies under this chapter, a violation of [8] this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2.
- [9] Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

The language of the statute raises a number of issues for our client that we would like to discuss with you, including the following:

- Does "And" Means "Or"? Sections [1][a] & [b] refer to "patient-identifiable" 1. information and prescriber-identifiable." We would like to discuss whether use of the conjunction "and" means both "and" and "or" so that covered entities would be restricted only in licensing, transferring, using or selling data that contained both "patient-identifiable information" and "prescriber-identifiable information" or whether the restriction would apply to data that contained either "patient identifiable information" or "prescriber identifiable information."
- "Identifiable". Sections [1][a] & [b] use the word "identifiable". We would like to discuss whether the term refers to (a) information which is readily-identifiable based upon the information provided by the pharmacy (or other data supplier), (b) information constituting "identifiable information" pursuant to HIPAA, or (c) information that has any chance of reidentification when combined with information from any other source (public or private; existing now or in the future).
- 3. Does "Other Similar Entities" Include IMS? Section [3] delineates a list of covered entities and concludes with subsection [3][e] with the term "other similar entity." The preceding list of entities all appear to be entities that serve a health care intermediary function, i.e., the function of prescribing, filling, or paying for prescribed pharmaceuticals, or communicating between those entities that perform these functions. IMS Health is not an entity that serves any of these functions, so we do not see the statute as having *direct* application to IMS Health. We would like to discuss whether the term "other similar entity" in section [3] nevertheless includes companies such as IMS Health.

- 4. May "Limited Purposes" be "Commercial"? Section [4] provides that the covered entities may not supply covered data for "commercial purposes," but it excludes from the definition of "commercial purposes" seven "limited purposes." IMS may acquire covered data from covered entities and sell the data to third parties for one of these limited purposes. For example, Section [4][e] identifies "health care research" as excluded from the definition of "commercial purpose"). That health care research might allow the purchaser of the covered data to engage in activities that would be profitable to it. In addition, most health care research supports outcomes or practices that are commercially beneficial to someone; if sponsored or conducted by a commercial entity, would it be regarded as "health care research" or a "commercial purpose"? We would like to discuss how you would distinguish restricted "commercial purpose" activities from permitted "limited purposes" activities, and under what circumstances these latter activities would violate the statute.
- Whose Purpose Governs? The statute prohibits the transfer of covered data only 5. for certain purposes, but does not state whether it is the purpose of the acquirer of the data, the provider of the data, or both that determines the purpose of the transfer. For example, the purpose of a pharmacy for selling information to IMS may be simply to make a profit from the sale of the information. IMS may acquire covered data from a covered entity that it may analyze and sell the data to third parties. A third party may acquire the data from IMS both for "commercial purposes" as that term is defined and for non-commercial purposes (e.g., "health care research"). We would like to discuss whose purpose determines how to characterize the purpose of a license, transfer, use or sale of covered data?
- What Does "As Otherwise Provided by Law" Mean? Section [4][f] excludes from the term "commercial purpose" the term "as otherwise provided by law." We are not aware of any laws that would limit the term "commercial purpose" as it is used by this statute other than section [7] of the statute itself. We would be interested in your views regarding whether the term "as otherwise provided by law" actually limits the meaning of the term "commercial purpose."
- How Would Dual Purposes be Treated? Section [5] specifically includes various purposes within the term "commercial purpose." Covered data may be licensed, transferred, used or sold by a covered entity for a purpose such as health care research and also for a purpose such as advertising. For example, data might be sold to IMS both for health care research and for advertising by a third party. We would like to discuss whether the license, transfer, use or sale of covered data from covered entities for such dual purposes violates the statute.
- If Data Merely "Could be Used" for a Prohibited Purpose May the Data be Sold? Section [5] defines "commercial purpose" as including, but not limited to advertising, marketing, promotion and "any activity that *could* be used to . . . " to perform the three delineated functions.

(Emphasis added). We would like to discuss whether the license, transfer, use, or sale of covered data by a covered entity that merely "could be used" for a prohibited commercial purpose, but which would not be used for such a purpose, would violate the statute. Also, since the definition is not all inclusive, what other purposes are regarded as prohibited commercial purposes?

- May Data be Used to Verify Zip Codes, Geographic Areas, & Specialties? Section [7] provides that "nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region or medical specialty for commercial purposes." The apparent intent of this section is to allow the continued licensing, transfer, use, and sale of covered data by covered entities to companies like IMS so that they may continue to provide data to third parties concerning which drugs are prescribed in which zip codes and geographic areas and by which types of medical specialists. Thus, for example, IMS could acquire from a covered entity covered data showing that Dr. John Smith prescribed Drug X to patient Y. IMS then could use that data to determine that the prescription had been written by a cardiologist (i.e., a medical specialty) whose office is located in the City of Concord, the County of Merrimack, and the 03301 zip code, and report that data, aggregated with other such data, to third parties without the identities of either the prescribers or the patients. We would like to discuss with you whether this is a proper interpretation of the new law.
- May Data be Received if it is Not Used? If section [7] does not allow the use of 10. prescriber-identifiable data in the manner described in paragraph 9, may IMS nevertheless acquire prescription records that contain prescriber-identifiable data if after the acquisition and prior to any use of the records IMS removes the prescriber-identifiable data. In this scenario, IMS then could use the remaining data in the prescription records to produce reports based on zip code, geographic region or medical specialty.
- Does the Statute Extend to Information Outside New Hampshire? Information relating to prescriptions dispensed in New Hampshire pharmacies flows outside of New Hampshire in the ordinary course of business for various purposes (e.g., adjudication of third party pharmaceutical benefits claims; operation and management of retail chain pharmacies). We would like to discuss with you whether this information existing outside the state of New Hampshire is subject to the restrictions of the new law.
- What Action Will the State Take to Enforce the Statute? RSA 318:55 provides that any person violating the provisions of chapter 318, except as otherwise provided, shall be guilty of a misdemeanor if a natural person, or guilty of a felony if any other person. It also provides that a civil penalty not to exceed \$5,000 may be imposed upon any person who willfully or repeatedly violates any provision of chapter 318. RSA 318-B:26 XI provides that any person who violates any provision of chapter 318-B for which a penalty is not provided by other paragraphs shall be guilty of a class B felony if a natural person, or guilty of a felony if any other person.

Section 8 of House Bill 1346 specifies that "a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2" and section 9 provides that "Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section." New Hampshire Revised Statutes Annotated § 358-A:4 authorizes the Attorney General to enforce the House Bill 1346 by action for a temporary and permanent injunction, by seeking civil penalties up to \$10,000 for each violation, and for appointment of a receiver to prevent future violations.

New Hampshire Revised Statutes § 358-A:9 further authorizes dissolution of any corporation for habitual violation of injunctions under section 358-A:4.

If IMS continues to acquire information from pharmacies in New Hampshire that identifies individual prescribers, as it has done for approximately 13 years -- for the purpose of aggregating the information, analyzing the information, and licensing, selling, or transferring the information, including information showing the prescription practices of individual prescribers, to pharmaceutical companies so that those companies can use the information for advertising, marketing and promotion and to engage in activities to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force -- would the State seek any of the remedies authorized by the statute against IMS, pharmacies from which IMS acquired the prescription information, or the pharmaceutical companies to which IMS sold the information?

We understand that however the State might elect to proceed under the statute that this would not ensure that private persons would not seek relief authorized by the statute under section 358-A:10, but any clarification that you can provide regarding the State's intention to enforce the statute would be useful in assessing our client's rights and obligations at this time.

I look forward to discussing these issues with you in the near future. I will call you later today or tomorrow to arrange a meeting next week.

Very truly yours,

ames P. Bassett

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